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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,919	05/10/2001	Qingsheng Zhu	279.330US1	4736

21186 7590 04/11/2003

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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 04/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/852,919	ZHU ET AL.
	Examiner Frances P. Oropeza	Art Unit 3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 28 January 2003.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) Claim(s) 9 is/are allowed.
- 6) Claim(s) 1-8 and 10-20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> . | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Newly submitted claims 21-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

1) In newly submitted independent claim 21, an apparatus is claimed that limits a signal to a first strength during a refractory period and to a second strength during a non-refractory period. The originally elected apparatus claim, independent claim 10, does not include limitations on the strength of the signal.

2) In newly submitted independent claim 24, an apparatus is claimed that provides an electrical signal generating device and a lead with first and second electrodes. The originally elected apparatus claim, independent claim 10, includes a heart rhythm sensing unit, not an electrical signal generating device, and a lead, but does not provide the two electrodes.

Since the Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-25 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Amendment filed 1/29/03***

2. The Applicant's amendment filed 1/29/03 has been fully considered. The amendment to claim 10 successfully overcomes the rejections of record for claims 10-14 and 16-20, hence these rejections are withdrawn. A new rejection is established for claims 1-8, 10-14 and 16-20. The Examiner has attempted to address the Applicant's arguments by clarifying the rejections.

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3. In the previous office action, claim 15 was indicated as containing allowable subject matter, however after further consideration, rejection of this claim is deemed appropriate. A new grounds of rejection for claim 15 is established in paragraph 6 of this action.

***Claim Rejections - 35 USC § 103***

4. Claims 1-3, 6-8, 10-14, 16, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247) and further in view or Eggers et al. (US 4998933).

Chekanov discloses a method of prevention and treatment of atherosclerosis in blood vessels, including the coronary artery (col. 9 @ 10-13). The implantable generator (25) (col. 2 @ 25-34) includes therapy circuits and one or two leads (col. 3 @ 42-49) to create the low-frequency non-excitatory electrical field that prevents plaque build-up in the coronary artery of the heart muscle.

Chekanov discloses the claimed invention except for:

- the lead including an electrode patch (claims 2 and 12),
- spacing the electrical fields about 10 seconds apart (claims 6 and 17), and
- the lead having two electrodes (claims 7 and 14).

Dev et al. disclose a device to dilate vessels using electrical fields to prevent plaque build-up (col. 2 @ 47-51; col. 6 @ 21-27) and teach that it is known: 1) to apply the method to the coronary artery, using an exo-luminal electrode (known in the cardiac art as related to the heart to optionally be an electrode patch) to establish the electrical field, 2) to space the electrical fields about 10 seconds apart, and 3) to provide two electrodes. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

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method of prevention and treatment of atherosclerosis in a blood vessel as taught by Chekanov, with the following elements as taught by Dev et al.:

- the lead including an electrode patch (claims 2 and 12) read as exo-luminal placement of the electrode in the heart for treatment of the coronary artery (col. 6 @ 28-35) to provide an electrode that enable creation of a broad electrical field enabling treatments of large areas of cardiac tissue,
- spacing the electrical fields about 10 seconds apart (claims 6 and 17) (c 7 @ 45-46) where one second or longer is read as about 10 seconds, to have a pulse timing sequence that is effective in treating plaque build-up, and
- the lead having two electrodes (claims 7 and 14) (col. 8 @ 59-64) to enable versatility in the creation of the electrical field.

Modified Chekanov discloses the claimed invention except the electrode field being generated such that the electrical field does not interfere with the heart rhythm.

Eggers et al. teach creating current flow along flux lines using stimulation that does not interfere with the natural pacing of the heart for the purpose of treating plaque safely. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation that does not interfere with the natural pacing of the heart in the modified Chekanov system in order to reduce the plaque in the heart while avoiding the creation of arrhythmias that lessen cardiac efficiency and potential create life threatening conditions (col. 3 @ 38-45; col. 6 @ 43-54).

5. Claims 4, 5, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Dev et al. (US 6347247) and further in view or Eggers et al. (US 4998933) and further in view of KenKnight et al. (US 6317615). As discussed in paragraph 4 of this action, modified Chekanov discloses the claimed invention except for sensing a heart rhythm and generating a non-excitatory electrical field after the heart depolarization.

KenKnight et al. disclose an apparatus to prevent plaque build-up (col. 1 @ 31-45) in a coronary artery (col. 13 @ 5-8). The pulse generator (140) includes an electrogram analysis circuit (222). KenKnight et al. teach that it is known to sense a heart rhythm and generate a non-excitatory electrical field after the heart depolarization (col. 2 @ 54-58). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method of prevention and treatment of atherosclerosis in a blood vessel as taught by modified Chekanov, with the sensing of the heart rhythm and generating a non-excitatory electrical field after the heart depolarization as taught by KenKnight et al. to ensure the electrical pulses and resulting electrical fields do not adversely impact the cardiac cycle.

6. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over KenKnight et al. (US 6317615) in view of Chekanov (US 6201991) and further in view or Eggers et al. (US 4998933).

KenKnight et al. disclose an apparatus to prevent plaque build-up (col. 1 @ 31-45) in a coronary artery (col. 13 @ 5-8). The pulse generator (140) includes an electrogram analysis circuit (222). A non-excitatory electrical field is generated after the heart depolarization at a level less than needed to capture the tissue (col. 2 @ 54-58; col. 4 @ 47-60).

KenKnight et al. discloses the claimed invention except for the system having two leads.

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Chekanov discloses a method of prevention and treatment of atherosclerosis in the coronary blood vessel and teaches the use of a generator that includes therapy circuits and a system that includes one or two leads to create an electrical field to prevent plaque build-up. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus to prevent plaque build-up as taught by KenKnight et al., with the system having two leads to allow diverse electrical fields to be created based on the patient's needs (col. 3 @ 42-49; col. 9 @ 10-13).

Modified KenKnight et al. disclose the claimed invention except the electrode field being generated such that the electrical field does not interfere with the heart rhythm.

Eggers et al. teach creating current flow along flux lines using stimulation that does not interfere with the natural pacing of the heart for the purpose of treating plaque safely. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used stimulation that does not interfere with the natural pacing of the heart in the modified Chekanov system in order to reduce the plaque in the heart while avoiding the creation of arrhythmias that lessen cardiac efficiency and potential create life threatening conditions. (col. 3 @ 38-45; col. 6 @ 43-54).

*Allowable Subject Matter*

7. Claim 9 is allowable.

*Statutory Basis*

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

4/1/03

*Angela D. Sykes*

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